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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,042	02/19/2002	Donald C. Roe	8430	4980

27752 7590 11/28/2006

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EXAMINER	
KOPPIKAR, VIVEK D	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/078,042	ROE ET AL.	
	Examiner	Art Unit	
	Vivek D. Koppikar	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/2/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-10 have been examined in this application. This Final Office Action is in response to the "Amendments" and "Remarks" filed on October 2, 2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The term "medically relevant" is not described in the specification. In the Remarks filed on October 2, 2006, applicants stated that the term "medically relevant" appears on page 9 of the specification between lines 14-18. However, the specification filed by the application on February 19, 2002 was examined and the term "medically relevant" does not appear on the cited portion of the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "medically relevant" in the claims renders them indefinite. It is not

clear what types of data the term "medically relevant" are supposed to include or exclude from a reading of the specification.

For the purposes of examination, the examiner will interpret the term "medically relevant" to include any type of health data or any type of data on vital statistics or information regarding a patient.

To overcome this rejection, the examiner recommends filing a Request for Continued Examination (RCE) and amending the claims so that the term "medically relevant" is replaced with more descriptive types of data that the applicants deem to be "medically relevant" data.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1 and 5-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of US Patent Number 4,448,203 to Williamson.

A) As per claim 1, a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

c) at least one data analysis mechanism generating insights relevant to a particular health condition wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Sheehan: Col. 7, Ln. 4-18) (Note: In Sheehan the data analysis mechanism is a group of population analysis because the images are compared to patterns or templates stored in the memory of the data acquisition and measurement device (computer); see Sheehan (Col. 7, Ln. 7-18); and

d) an information presentation mechanism displaying the insights relevant to the particular health condition (Sheehan: Col. 4, Ln. 54-67).

Sheehan does not teach that the insights are medically relevant insight, however, this feature is commonly known in the health care industry as evidenced by Williamson (Col. 1, Ln. 10-19). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Williamson to have provided medical professionals with an improved means of detecting abnormal conditions in a patient, as recited in Williamson (Col. 1, Ln. 5-10).

(B) As per claim 2, in the system of Sheehan the at least one data analysis mechanism further comprises data analysis software (Sheehan: Col. 2, Ln. 58-62 and Col. 7, Ln. 47-59).

(C) As per claim 5, in the system of Sheehan the at least one data measurement mechanism includes a sensor (Sheehan: Col. 1, Ln. 29-38).

(D) As per claim 6, Sheehan teaches a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group: a tablet PC, voice recognition, and telemetry based systems (Sheehan: Col. 2, Ln. 34-46 and Col. 8, Ln. 18-32);

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Sheehan: Col. 7, Ln. 4-18); and

d) an information presentation mechanism displaying the insights relevant to the particular health condition (Sheehan: Figures 3 and 5 (220) and Col. 4, Ln. 54-67)

(E) As per claim 7, in the system of Sheehan at least one data acquisition mechanism includes a handheld device selected from the group: a PDA and a handheld PC (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32)

(F) As per claim 8, the system of Sheehan includes:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Col. 7, Ln. 4-18 and Col. 4, Ln. 54-67); and

d) an information presentation mechanism displaying the insights relevant to the particular health condition, wherein the at least one information presentation mechanism is selected from the group: a graphical summary screen, an icon based summary screen, a help guide, an anthropomorphic help guide, and synthesized speech (Sheehan: Figures 3-5; Col. 4, 54-67 and Col. 6, Ln. 47-59).

Sheehan does not teach that the insights are medically relevant insight, however, this feature is commonly known in the health care industry as evidenced by Williamson (Col. 1, Ln. 10-19). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Williamson to have provided medical professionals with an improved means of detecting abnormal conditions in a patient, as recited in Williamson (Col. 1, Ln. 5-10).

(G) As per claim 9, Sheehan teaches a method for improving the health of an individual (Sheehan: Abstract) including the steps of:

a) selecting at least one health parameter appropriate for the particular individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional (Sheehan: Col. 4, Ln. 12-18);

b) measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: Col. 2, Ln. 23-46);

c) acquiring the data for storage and subsequent analysis (Sheehan: Col. 2, Ln. 23-46);

d) analyzing the data via at least one data analysis mechanism to define out-of-control situations requiring intervention, potential causes or remedies wherein the data analysis mechanism

performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Sheehan: Col. 7, Ln. 4-18); e) presenting the information (alert) to the individual, caregiver, or medical professional (Sheehan: Col. 6, Ln. 47-59 and Col. 7, Ln. 13-19).

Sheehan does not teach that the insights are medically relevant insight, however, this feature is commonly known in the health care industry as evidenced by Williamson (Col. 1, Ln. 10-19). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Williamson to have provided medical professionals with an improved means of detecting abnormal conditions in a patient, as recited in Williamson (Col. 1, Ln. 5-10).

(H) As per claim 10, in the method of Sheehan the information presented is selected from the group: statistical analysis, out-of-control points, control rules violations, specification violations, medical limit violations, medical condition related information, advertising for products related to the individual's medical condition or health event, help guides, summary screens (Sheehan: Figures 3 and 5 (220); Col. 4, Ln. 62-68 and Col. 7, Ln. 4-18).

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Williamson, as applied to Claim 1, above, and in further view of US Patent Number 5,920,478 to Ekblad.

(A) As per claim 3, Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performance, however, this feature is taught by Ekblad (Col. 11, Ln. 52-59). At the time of the invention, it would have been obvious for one of ordinary skill in the art

to have modified the system of Sheehan with the aforementioned feature from Ekblad with the motivation of having a means of allowing adaptive updating in response to changes (variations) in data, as recited in Ekblad (Col. 11, Ln. 52-59). In the alternative, the examiner takes Official Notice that this feature is well known in the art and at the time of the invention one of ordinary skill in the art would have been motivated to have modified the system of Sheehan with this aforementioned feature with the motivation of having a means to set the control limits so that they reflected and were up to date to changes in the raw historical performance data that was obtained from various patients.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan, as applied to Claim 1, above, and in further view of US Patent Number 6,642,592 to Loman.

(A) As per claim 4, Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration, however, this feature is taught by Loman (Col. 5, Ln. 14-16). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Loman with the motivation of having a fault resolution means (Loman: Col. 10-14) to detect faults and failures within the system of Sheehan.

Response to Arguments

10. With regards to the Applicant's arguments filed on October 2, 2006 regarding the term "medically relevant", these arguments have been considered but are moot in view of the new grounds of rejection.

With regards to the applicants arguments on page 10, paragraph 2 of the "Remarks" section that Sheehan does not disclose any steps in which there is a measuring of a health

parameter, the Examiner would like to point that Sheehan does in fact teach measuring (Col. 4, Ln. 36-45). Furthermore, the applicants' specification nor the "Remarks" specify what type of data the applicants are attempting to claim by the use of the term "health parameter."

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

12. Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

11/16/2006

C. LUKE GILLIGAN
Primary PATENT EXAMINER